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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/601,655 08/04/00 SAKANAKA

0 20001081A

EXAMINER

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HM12/1106

ROBINSON, E

ART UNIT	PAPER NUMBER
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1625

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DATE MAILED:

11/06/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/601,655	Applicant(s) Sakanaka Et. Al.
	Examiner Binta Robinson	Group Art Unit 1625

Responsive to communication(s) filed on _____

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle* 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

Claim(s) 1, 11, and 13-18 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) _____ is/are rejected.

Claim(s) 2-10, 12, and 19 is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --

Art Unit: 16²⁵

DETAILED ACTION

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 11 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). The recitation of the term, "use" is non-statutory. The claims should be directed to a compound.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. The phrase "antifungal agent" in claims 16 and 17 is not a statutory class of invention.

The term "pharmaceutical composition" is suggested.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. Claims 1, 11, 13, 14, 15, 16, 17, and 18 are rejected under 35 U. S. C. 102(a) as being anticipated by Hanafi et. al. (See Reference U).

Hanafi teaches the instant compounds, 2-Butenoic acid, 2-methyl-, (3S, 6S, 7R, 8R)-3-[(3-hydroxy-4-methoxy-2-pyridinyl)carbonyl]amino]-6-methyl-4, 9-dioxo-8-(phenylmethyl)-1, 5-dioxonan-7-yl ester, (2E)- and Butanoic acid, 3-methyl-, (3S, 6S, 7R, 8R)-3-[(3-hydroxy-4-methoxy-2-pyridinyl)carbonyl]amino]-6-methyl-4,9-dioxo-8-(phenylmethyl)-1,5-dioxonan-7-yl ester. At page 543, see the instant compounds.

5. Claims 1, 11, 13, 14, 15, 16, 17, and 18 are rejected under 35 U. S. C. 102(a) as being anticipated by Shimano et. al. (August 1998) (See Reference V).

Shimano et. al. teach the instant compound, Antimycin A₃. At page 12746, see the instant compound.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 11, 13, 14, 15, 16, 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimano (August 1998). (See Reference V).

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Shimano et. al. teach a class of Antifungal Dilactones. At page 12746, see compound UK-2A, where R1 is isobutanoyl. At R1 of the instantly claimed compounds, this radical represents isovaleryl. The difference between the prior art reference and the instantly claimed compound is at the R1 position of the claimed compounds. The prior art reference discloses the same compound except for a methylene linkage rather than the ethylene linkage claimed by the applicant. The claimed alkyl substituent is a homolog of the disclosed ethyl substituent. Homologs are a class of compounds differing only by a methylene linkage and possessing similar properties based on their similar structures. Accordingly, it would have been obvious to one of ordinary skill in the art to replace the methylene linkage in the class of Antifungal Dilactone systems in view of their closely related structures and expectation of similar chemical properties.

Claims 1, 11, 13, 14, 15, 16, 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimano (April 1998). (See Reference W).

Shimano et. al. teach a class of Antifungal Dilactones. At page 4363, see compounds UK-2A and Antimycin A2, where R1 is isobutanoyl. At R1 of the instantly claimed compounds, this radical represents isovaleryl. The difference between the prior art reference and the instantly claimed compound is at the R1 position of the claimed compounds. The prior art reference discloses the same compound except for a methylene linkage rather than the ethylene linkage claimed by the applicant. The claimed alkyl substituent is a homolog of the disclosed ethyl substituent. Homologs are a class of compounds differing only by a methylene linkage and possessing similar properties based on their similar structures. Accordingly, it would have been

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obvious to one of ordinary skill in the art to replace the methylene linkage in the class of Antifungal Dilactone systems in view of their closely related structures and expectation of similar chemical properties.

7. Claims 2-10, 12, and 19 are objected to because they are based on a rejected claim.
8. The Shimano Reference noted as an X reference on the International Search Report has been considered and is an X reference.
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta Robinson whose telephone number is (703)306-5437. The examiner can normally be reached on Monday through Friday from 9:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. John Kight, can be reached on (703)308-0204. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

BMR

BMR
November 2, 2000


John Kight
SUPERVISOR EXAMINER
Group 160
TWD